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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,298	03/09/2004	Masato Mitsuhashi	HITACHI.055CP2	9108

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EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
09/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/796,298	MITSUHASHI, MASATO	
	Examiner	Art Unit	
	FRANK W. LU	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73,75,77-92,215,217-237 and 240* is/are pending in the application.

4a) Of the above claim(s) *89,90,220-230 and 234-237* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73, 75, 77-88,91,92, 215,217-219,231-233,and 240* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 February 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on April 28, 2009 has been entered. The claims pending in this application are claims 73, 75, 77-92, 215, 217-237 and 240 wherein claims 89, 90, 220-230, and 234-237 have been withdrawn due to species election and election by original presentation. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment filed on April 28, 2009. Claims 73, 75, 77-88, 91, 92, 215, 217-219, 231-233, and 240 will be examined.

Specification

2. The amendment filed on April 28, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by paragraphs [0150] and [0151] of the original disclosure suggested by applicant is as follows: "Δ shows p21 mRNA for the control stimulation" and "◊ shows FasL mRNA for the control stimulation" in paragraphs [0055] and [0151] of the amended specification (see pages 2 and 7 of applicant's remarks).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

3. Claim 73 is objected to because of the following informalities: "target mRNA" in line 1 of step (h) should be "said target mRNA".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. New Matter

Claims 215, 217-219, 231-233, and 240 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

First, although the specification describes that "by adding multiple antisense primers for different targets, each gene can be amplified from the aliquot of cDNA, and oligo(dT)-derived cDNA in the GenePlate can be stored for future use" (see page 15, paragraph [0080]), paragraph [0080] of the specification suggested by applicant does not describe "a plurality of different antisense primers for different target mRNAs are present in the lysis buffer" as recited in dependent claim 217. Second, the recitation "the target mRNA is mRNA responsible for apoptosis development, and wherein the quantification of mRNA is used to test the side effects of anti-cancer drugs that induce mRNA responsible for apoptosis development" is added to newly dependent claim 233. Although the specification describes to test the side effects of anti-cancer drugs on white blood cells (see original filed claim 29) and describes that the genes related to apoptosis are candidate genes for anti-leukemia drugs (see Table 1 in page 8), Table 1 of the specification suggested by applicant fails to define or provide any disclosure to support

such claim recitation in claim 233 because anti-cancer drugs recited in original filed claim 29 is not limited to anti-cancer drugs on white blood cells and may include other drugs which are not anti-cancer drugs on white blood cells. Furthermore, anti-cancer drugs recited in original filed claim 29 is not limited to anti-cancer drugs that induce mRNA responsible for apoptosis development and may include other drugs which are not anti-cancer drugs that induce mRNA responsible for apoptosis development such as a drug that increases human immunity. Third, nowhere in the specification describes "quantifying the target mRNA by quantifying the cDNA in said cDNA solution" recited in step (h) of claim 215, "each of said different mRNAs is amplified from the cDNA formed by extension of the antisense primers in step (g)" recited in claim 218, and "each of said different mRNAs is amplified from the cDNA formed by extension of the immobilized oligo(dT) in step (g)" recited in claim 240. Furthermore, in applicant's remarks filed on April 28, 2009, applicant does not indicate which parts in the specification supports above claim limitations recited in claims 215, 218, and 240.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 73, 75, 77-88, 91, 92, 215, 217-219, 231-233, and 240 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 73 is rejected as vague and indefinite because it is unclear that the definite quantity of the target mRNA is the quantity of total mRNA from leukocytes or the quantity of specific mRNA encoding for a specific gene. Please clarify.

9. Claim 73 is rejected as vague and indefinite in view of steps (d) to (h). Since step (d) does not require that spiked control RNA is mRNA, if spiked control RNA is not mRNA but is tRNA, the spiked control RNA can not be immobilized on the oligo(dT) plate so that the percent recovery of the spiked control RNA in a solution comprising the lysis buffer is not comparable with the percent recovery of the target mRNA in the oligo(dT) plate and the definite quantity of the target mRNA recited in step (h) cannot determined based on the percent recovery of the spiked control RNA in the solution comprising the lysis buffer determined in step (g). Please clarify.

10. Claim 215 is rejected as vague and indefinite in view of step (g). Since step (g) does not require to perform the extension of both the immobilized oligo(dT) and the antisense primers in the presence of a DNA polymerase with 3' to 5' exonuclease activity and it is known that reverse transcriptase does not contain 3' to 5' exonuclease activity, it is unclear how the cDNA formed by extension of the antisense primers can go into solution as a result of displacement by the cDNA formed by extension of said oligo(dT) without heat denaturation of said target mRNA and said cDNA formed by extension of the antisense primers. Please clarify.

11. Claim 215 is rejected as vague and indefinite in view of step (h). Since claim step (g) of claim 215 require that the cDNA formed by extension of the antisense primers goes into solution as a result of displacement by the cDNA formed by extension of said oligo(dT) without heat denaturation of said target mRNA and said cDNA formed by extension of the antisense primers, if there is a DNA polymerase with 3' to 5' exonuclease activity in step (g), the cDNA formed by extension of the antisense primers in step (g) in the solution becomes cDNA fragments due to 3' to 5' exonuclease activity of the DNA polymerase. Since step (h) does not indicate how to correlate the target mRNA with the cDNA in said DNA solution, it is unclear why target mRNA can be quantified by quantifying the cDNA in said DNA solution. Please clarify.

12. Claim 218 is rejected as vague and indefinite. Since claim step (g) of claim 215 require that the cDNA formed by extension of the antisense primers goes into solution as a result of displacement by the cDNA formed by extension of said oligo(dT) without heat denaturation of said target mRNA and said cDNA formed by extension of the antisense primers, if there is a DNA polymerase with 3' to 5' exonuclease activity in step (g), the cDNA formed by extension of the antisense primers in step (g) in the solution becomes cDNA fragments due to 3' to 5' exonuclease activity of the DNA polymerase. Thus, it is unclear how each of said different mRNAs can be amplified from the cDNA formed by extension of the antisense primers in step (g). Please clarify.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on (571)272-0763.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /
Primary Examiner, Art Unit 1634
August 26, 2009